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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,629

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Youngro Byun

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EXAMINER

SELLMAN, CACHET I

ART UNIT

PAPER NUMBER

1792

MAIL DATE

DELIVERY MODE

07/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,629	Applicant(s) BYUN ET AL.	
	Examiner CACHET I. SELLMAN	Art Unit 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1-4, 8-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 1 recites the limitation "the hydrophobic heparinized polymer" in lines 13 and 15. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-12 and 16 are is rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. in view of Bernacca and Tsang et al. (US 5955588)

Ding et al. discloses a process for coating a medical device (i.e. stent) (see col. 4, lines 58-67) with an underlayer (reservoir layer) and a top layer. The coating allows for timed and prolonged pharmacological activity on the surface of the medical device (see abstract). The reservoir layer comprises a polymer and a biologically active material (see col. 5, lines 31-37). The reservoir layer is formed by combining the polymer and the active agent with a solvent and is then applied to the stent (see example 1).

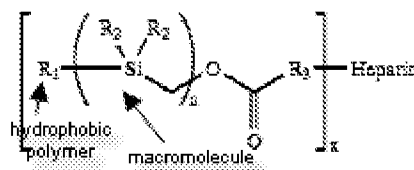
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The toplayer comprises an ionic surfactant drug complex which can also contain a polymer (see col. 8, lines 15-30). The drug used in the top layer is heparin (see examples).

Ding et al. fails to teach that the second layer comprises a macromolecule, a hydrophobic material and heparin bound together with covalent bonds, and cleaning the stent with a washing agent as required by **claim 1**.

However, it was well known in the art at the time the invention was made to clean a stent prior to coating in order to remove contaminants and to insure that the coatings will adhere to the stent such as taught by Bernacca et al (US 6251142) therefore one would have been motivated to wash the stent as taught by Bernacca et al. prior to coating in order to ensure sufficient adherence of the coating to the stent.

Tsang et al. teaches a non-thrombogenic coating that is applied to the blood contacting surfaces of medical devices which prevents heparin from leaching out from the coating as a result of breaking of ionic bonds and the covalent bond is not disrupted by the presence of ionic species in the blood that may come in contact (see col. 4 - col. 5). The coating comprises



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process of Ding et al. to include the top coating

comprising the composition of Tsang et al. One would have been motivated to do so because both are directed towards controlled rate release in medical devices especially stents which comprise heparin. Furthermore, Tsang et al. teaches that such a coating improves biocompatibility and high bioactivity which does not easily break or leach out heparin.

The underlayer can comprise of more than one drug/ bioactive agent (see col. 7, lines 60-65) as required by **claim 2**. The polymer and agent mixture can be applied by dipping the stent into the mixture or spraying (see col. 7, lines 29-31) as required by **claims 3 and 4**.

As started above, Ding et al. modified by Byun et al. teach the use of the top coating which is used to prevent burst release by adding the rate controlling layer as required by **claim 5**.

As stated above the composition applied to the medical device is an antithrombogenic coating as required by **claim 6**.

The polymer film can be formed of polyolefins, polyurethanes, silicones, polyesters, polycaprolactones (see col. 5, lines 37-64) as required by **claim 8**. The biologically active agent can be antithrombotic, anticoagulants, antiplatelet, antiinflammatory, antibiotics, etc. (see col. 6, lines 23-40) as required by **claim 9**. The first layer can comprise a second active agent as required by **claim 10**.

The macromolecule can be a synthetic macromolecule such as polysiloxanes as required by **claims 11-12**.

Response to Arguments

6. Applicant's arguments, see pages 13-17 filed 6/20/2008, with respect to the rejection(s) of claim(s) 1-16 under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CACHET I. SELLMAN whose telephone number is (571)272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman

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Examiner
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/C. I. S./
Examiner, Art Unit 1792

/William Phillip Fletcher III/
for Timothy H. Meeks, SPE of Art Unit 1792/1700